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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/618,759	07/18/2000	Howard R. Levin	3659-10	9602
23117	7590	11/17/2003	EXAMINER	
NIXON & VANDERHYE, PC 1100 N GLEBE ROAD 8TH FLOOR ARLINGTON, VA 22201-4714			DEAK, LESLIE R	
			ART UNIT	PAPER NUMBER
			3762	16
DATE MAILED: 11/17/2003				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/618,759

Applicant(s)

LEVIN ET AL.

Examiner

Leslie R. Deak

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 10 July 2003.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-48 is/are pending in the application.
 4a) Of the above claim(s) 5 and 16 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-4, 6-15 and 17-48 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) 1-48 are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 25 August 2003 is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
 a) The translation of the foreign language provisional application has been received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413) Paper No(s). _____.
2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) Notice of Informal Patent Application (PTO-152)
3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4-10. 6) Other: _____

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-4, 6-15, 27-26, and 27-48, drawn to a method for removing fluid from a patient including determining and maintaining a specific percentage of cardiac output as the blood flow in the circuit, classified in class 604, subclass 5.01.
 - II. Claim 5, drawn to a method for removing fluid from a patient including determining and maintaining a specific rate of the removal of blood, classified in class 604, subclass 5.01.
 - III. Claim 16, drawn to a method of removing fluid from a patient with a membrane of specific transmembrane pressure, classified in class 604, subclass 6.09.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions in Group I and Group III are related as subcombination and combination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the method in Group I does not require the determination and maintenance of a specific blood

removal rate as required in Group II. The subcombination has separate utility such as an independent method for fluid removal from the patient.

3. Inventions in Group I and III are related as subcombinations disclosed as usable together in a single combination. The subcombinations are distinct from each other if they are shown to be separately usable. In the instant case, the methods have separate utility as independent methods of fluid removal, but can be used together to maintain a specific percent of cardiac output in the circuit while using the filter with a specific transmembrane pressure. See MPEP § 806.05(d).

4. Inventions in Group II and Group III are related as subcombinations disclosed as usable together in a single combination. The subcombinations are distinct from each other if they are shown to be separately usable. In the instant case, the methods have utility as independent methods of fluid removal, but can be used together to maintain a specific rate of blood removal while using the filter with a specific transmembrane pressure. See MPEP § 806.05(d).

5. Because these inventions are distinct for the reasons given above and the searches required for the Groups are different, restriction for examination purposes as indicated is proper.

6. Applicant's election without traverse of Group I in a telephone conversation with examiner on October 30, 2003 is acknowledged.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 7 and 33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear whether applicant is intending to claim the methods used by a human kidney to filter blood. Such claiming of biological processes performed by the human body is non-statutory subject material, since the process being performed by the human kidney occurs in nature.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. Claims 1-4, 6, 8, 9, 13-15, 17-32, 34, 35, 39-42, 44-48, are rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,828,543 to Weiss, in view of US 5,211,849 to Kitaevich. Weiss discloses a system and method for filtering a patient's blood comprising of accessing a patient's circulation system through single or double needles, using a hollow-fiber membrane to filter out undesirable components of a certain size, depending on the desired procedure, and return filtered blood to the patient. The system and method comprise a controller that determines the rate of removal and return of fluid to and from the patient, which is based on patient

parameters, and the rate of filtration by adjusting the transmembrane pressure of the device, and operating various valves to alter flow through the device (see, generally, columns 3, 8, 9, 12, 14). Weiss discloses a bubble detector that sends a signal to the central processor to rectify the presence of air (see column 21). Weiss fails to specifically disclose fluid removal from the patient, but Kitaevich discloses that hemofiltration of patient blood often includes fluid withdrawal and further discloses that a controller determines the rate of fluid withdrawal based on input values (see column 3). Kitaevich discloses that his system comprises a series of pressure transducers that measure the pressure in the system (which may reflect a blockage) and transmits alarm signals to the controller which may halt the pumps (see column 6). Neither reference discloses the specific percent of cardiac output in the filtration system or the particular rate of removal claimed by applicant. However, both Weiss and Kitaevich disclose that such values may be adjusted and controlled by the controllers, which vary input/outflow pump speed and filtration rate. It would have been obvious to one having ordinary skill in the art at the time the invention was made to adjust the total patient blood flow through the system and the filtration rates of the Weiss and Kitaevich to those values claimed by applicant, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. See MPEP 2144.05.

With regard to claims 17 and 43 drawn to the shear rate of the blood through the filter, it is the position of the examiner that the structure of the device affects the shear rate of the blood through the filter as an inherent feature of the device. Therefore, claims

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drawn to the shear rate of the blood in the device do not patentably distinguish over the prior art of record.

11. Claims 10-12 and 36-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,828,543 to Weiss, in view of US 5,211,849 to Kitaevich, further in view of US 5,830,365 to Schneditz. Neither Weiss nor Kitaevich disclose that the patient blood comes from a vein, though Weiss discloses a single and double-needle patient access for hemodialysis. However, Schneditz discloses that his hemodialysis device with patient monitors accesses the patient blood supply via a fistula that is connected to the patient's vascular system. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to obtain blood from a fistula connected to a patient's vascular system in order to obtain a constant flow of blood for the filtration procedure.

Conclusion

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

- a. US 4,619,639 Nose et al
 - i. Low pressure blood filtration with feedback
- b. US 5,792,367 Mattison et al
 - ii. Dialysis with pressure and flow monitoring
- c. US 2002/0085951 A1 Gefland et al
 - iii. Feedback control of ultrafiltration

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie R. Deak whose telephone number is 703-305-0200. The examiner can normally be reached on M-F 7:30-5:00, every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 703-308-5181. The fax phone number for the organization where this application or proceeding is assigned is 703-305-3590.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0873.

Lrd

6 November 2003



ANGELA D. SYKES
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700